

NAFTA TECHNICAL WORKING GROUP ON PESTICIDES

PROGRESS REPORT

November 17, 1997

INTRODUCTION

The last meeting of the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG) on Pesticides was held in Ottawa, June 2-4, 1997. A report of the meeting and associated project sheets and workplans were distributed to stakeholders August 20, 1997. A meeting of the NAFTA Executive Board is scheduled for December 3-4, 1997 in Washington D.C. The purpose of the meeting is to review progress on the NAFTA projects and discuss emerging issues. In preparation, this report on the progress made on the individual projects since June has been prepared. The individual projects are organized in the same format as the information distributed on August 20. The full project sheets and workplans will be updated and circulated in preparation for the annual meeting of the full NAFTA TWG scheduled for June 1998 in Mexico.

REPORTS OF THE TECHNICAL SUBCOMMITTEES

A. Regulatory Capacity Building Subcommittee

A1. Spray Drift and Deposit Model

On September 11-12, 1997, the U.S. Environmental Protection Agency (EPA) held a public workshop on the Spray Drift Task Force Aerial Field Data. Representatives from regulatory agencies in both Canada and the U.S., industry, academia, and public interest groups participated in the workshop. The general consensus was that the aerial database was relatively sound with no major scientific problems. The next step is to present the spray drift task force data and model to the U.S. Scientific Advisory Panel (SAP) in December 1997. Given a positive reaction from SAP, further consultation will be initiated with stakeholders on the use of the model as a regulatory tool. The model will be available to PMRA and EPA for use as a regulatory tool by April 1, 1998.

A2. Harmonization of Environmental Fate and Toxicology Study Protocols

Environmental Fate

The Pest Management Regulatory Agency (PMRA) and EPA have formed working groups to discuss and make recommendations on specific issues. The Terrestrial Field Dissipation Studies guideline is on target with agreement having been reached on making composite samples from

replicates within each plot. It is anticipated that a draft guideline will be prepared by May 1998, with a final draft ready for review by the U.S. Science Advisory Panel in June 1998. Regarding the Aerobic Aquatic Metabolism protocol, agreement has been reached on the use of sterile controls and a water/sediment ratio of 10/1. Both countries are participating in revisions to the Organization for Economic Cooperation and Development (OECD) guideline on Adsorption/Desorption and will adopt that guideline when completed. A meeting was held in November in Washington, D.C., to discuss all the environmental fate protocol issues.

Environmental Toxicology

The PMRA and EPA have formed working groups to develop joint positions on specific issues and, where appropriate, to bring these forward for discussion through the OECD Test Guidelines Program. As data requirements for algae and non-target terrestrial plant testing are linked it is anticipated that the resolution of these issues will not meet the December 1997 deadline. The PMRA is currently examining the Canadian and U.S. plant testing approaches to focus the discussions. Non-target plant test guidelines and strategies are also being discussed by the OECD Working Group on Test Guidelines for Terrestrial Plant Testing on which EPA participates. Although final resolution is dependent on the OECD schedule, a joint position on terrestrial plant testing is planned for December 1998. The lemna foliar application protocol is currently under consideration by the same OECD working group. A PMRA/EPA meeting is scheduled in November 1997 to discuss outstanding issues. It is anticipated that review of non-target plant test guidelines and strategies by the U.S. Science Advisory Panel will be required.

A3. Canada-U.S. Map of Ecoregions for Terrestrial Field Studies

During an August 1997 meeting in Washington, DC, the PMRA/EPA project team evaluated a prototype, which included two ecoregions common to the U.S. and Canada, and combined U.S. and Canadian soil information and Canadian crop data. The project team will incorporate selected U.S. crop data for the two ecoregions to complete the demonstration prototype. The team also agreed to incorporate climatic information (soil temperature from the United Nations Food and Agriculture Organization (FAO) Soils Map of the World and rainfall data) in the near future. The project will be expanded with additional crops and the remaining ecoregions common to Canada and the U.S. The prototype was presented to Canadian pesticide industry representatives on November 5, 1997 in Ottawa, and to U.S. industry representatives, academia, and other government representatives on November 20, in Washington, DC. The industry consultation timeline has slipped one month; otherwise the project is on track.

Digitized maps are being compared to identify differences between the NAFTA Level II Ecoregion Map and the NAFTA residue map. Differences south of the border will be addressed by the US Team, north of the border by PMRA (Environmental Assessment Division (EAD) and Health Effects Division/Food Residues Exposure Assessment Section (HED/FREAS)). The issue is being discussed Nov 21 with EPA. Discussions between EAD and HED/FREAS of PMRA are planned for December.

A4. Electronic Submission and Review Project

In keeping with the commitment for a harmonized approach for implementing electronic capability for submitting and reviewing submission data, Canada, Mexico and the United States are signatories to a letter (dated October 20, 1997) advising the pesticide industry that when international electronic format specifications have been agreed to, the pesticide regulatory agencies will only accept electronic submissions in a format that complies with these specifications.

Implementation of the Computer Aided Dossier and Data Supply (CADDY) system

Close links have been established with those developing the Computer Aided Dossier and Data Supply (CADDY) submission and archiving standard within the European Union.

PMRA and EPA participated in a round of Beta-testing of the CADDY retrieval software in mid-October. This activity provided opportunities to:

- i) Analyze, design and document processes for in-processing and screening CADDY submissions, PMRA is completing a report on their analysis of 21 inch monitors;
- ii) Analyze, design and document processes to review CADDY submissions;
- iii) Train staff and registrants on in-processing, screening and review techniques.

A written report on the results of the beta-testing is being prepared for submission to the CADDY beta-test team in Europe in January 1998.

Work is continuing on the development within EPA and PMRA of Standard Operating Procedures (SOP's) for processing CADDY submissions. Canada has completed an initial assessment based on the data provided in the CADDY beta-test. However, due to the limited data available, SOPs for full processing of a complete submission cannot be developed at this time. Final decisions on the appropriate process for handling CADDY submissions are pending receipt of a full submission.

The final outcome will be a report to registrants and regulators prepared by the implementation teams evaluating all aspects of CADDY including proposed changes and opportunities for broader consultation.

Continuing Coordination by Global Regulatory Information Technology (GRIT) Sub-Group

Canada and the United States participate on the Global Regulatory Information Technology (GRIT) group. GRIT reports its activities to the OECD Pesticide Forum. Participants include representatives from the pesticide regulatory authorities in the United States, Canada, Australia, member states of the European Union, as well as, representation from the OECD Pesticide Forum

secretariat, the European Crop Protection Association, the American Crop Protection Association, and Canadian industry.

Current efforts are focussed on the preparation of an inventory and report on databases and related software and hardware that are used by countries and the pesticide industry which aid and support the pesticide regulatory process. The results will be presented at the OECD Pesticide Forum in February 1998 and will form the basis for a scoping document that considers alternatives and sets priorities for IT efforts.

Explore Other Electronic Submission and Review Opportunities

An important component of the PMRA project on process analyses and design has been hosting three interactive consultative sessions with industry. The reports of these sessions were distributed to participants and the international community such as members of GRIT and EPA. These will be available on the PMRA web site shortly.

One recommendation emerging from the consultative sessions was a proposal for conducting joint PMRA industry pilots to explore options to improve efficiency. Detailed project plans for the proposed pilots will be prepared for in time for the full NAFTA TWG in June 1998.

EPA is piloting use of software that compares current and proposed label text to improve the label review process. A draft SOP for processing and reviewing the label text has been developed. Training on use of the new software took place in late October and early November. A specific group of registrants who are required to make label changes have been invited to submit these changes electronically. The label text submissions are due January 15, 1998.

The proposal for the development a detailed project plan regarding the a single data base to manage information on US tolerances and Canadian MRLs has not been initiated.

A5. Regulatory Aspects of Disease and Pest Control Products and Methods in Aquaculture

A general procedure for exchange of information between the U.S. Food and Drug Administration (FDA) and PMRA has been put in place. With permission of the sponsor, reviews of cypermethrin have been exchanged between FDA and PMRA. Information sharing is also being arranged for an additional product. Plans are in progress for FDA attendance at the relevant PMRA Science Review meeting. A draft of an overview paper on integrated management of sea lice has been prepared and was distributed in November to a multi-stakeholder working group for comment and refinement. In line with the workplan a final version of the document will be available by July 1, 1998.

A6. Harmonization of EU-OECD Guidance Documents for Preparation and Presentation of Submissions by Industry and Preparation of Evaluation Reports by

Regulatory Agencies

This project is on schedule with OECD guidance on the preparation of dossiers/monographs expected to be ready for endorsement by the OECD Pesticide Forum in February 1998. At a September 1997 Dossier/Monograph Harmonization Meeting in Dublin, Canada and the United States were successful in obtaining placeholders for more detailed sections on efficacy, occupational/bystander exposure and residue data in the OECD guidance; in getting agreement to proceed jointly with a cross-reference to the various numbering systems in Canada, the United States, the European Union and other OECD countries, as available; and in gaining general support for more detailed Tier 1 quality checks along the lines of the PMRA screens. A discussion paper on the PMRA screening experience will be prepared in time for the February Pesticide Forum. In addition, a process to prevent divergence of the guidance during implementation by EU and OECD member states was proposed in response to Canadian concerns. Next steps will include development of an implementation plan for PMRA, EPA, and Mexico.

A7. Harmonization of Occupational/Bystander/Residential Exposure Assessment

Develop position papers on specific issues with recommendations for harmonization.

Resolution of the eleven issues considered in this project will facilitate work sharing and joint reviews. The majority of the position papers will be completed by December 1997. The project team will consider the recommendations outlined in the position papers and prepare an SOP document on harmonized approaches by April 30, 1998.

Cooperate in the Development of Post-Application Exposure Databases and Redesign of the Pesticides Handlers Exposure Database (PHED)

With respect to the two re-entry databases (Outdoor Residential (turf) and Agricultural), EPA, PMRA, and the California Department of Pesticide Regulation (California DPR) continue to participate in quarterly meetings of the U.S. Joint Regulatory/Industry Task Force Committee and work is on schedule.

Comments on PHED Version 2.0 have been received from PMRA and California DPR and have been incorporated. A second beta-test was undertaken in November, with a further test possible early in 1998 depending on user comments. Release of the revised PHED Version 2 is targeted for April 30, 1998. Harmonized guidelines on using and reporting of PHED have been prepared and are awaiting final approval by EPA, PMRA and California DPR.

Development of a Harmonized Post Application Exposure Assessment Guidance Document

The workshop on Pesticide Post-application Exposure Assessment (Toronto, October 6-8, 1997) was a joint effort of the PMRA and EPA, and was officially supported by OECD, with input from

the California DPR. The intent was two fold: to collect input from the participants for US EPA Series 875-Occupational and Residential Test Guidelines and to make the first steps towards OECD guidance documents on post-application exposure. It was attended by 60 invited experts in post-application assessment from 15 countries, including OECD countries. Regulatory agencies, industry and academia were represented.

The objectives of the workshop were achieved. It provided a forum for critical discussion of technical and scientific issues concerning agricultural, residential, and industrial post-application exposure to pesticides, and represents a basis for international harmonization on guidance for the conduct of post-application exposure studies. The final Workshop report including all recommendations will be available in December 1997. The harmonized Canada-US Guideline on Post Application Exposure Assessment is targeted for completion by July 31, 1998.

A8. Assessment of Feasibility of Probabilistic Tools and Methods for Ecological Assessments

In response to the U.S. Science Advisory Panel's recommendations, EPA initiated the Ecological Committee on the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Risk Assessment Methods (ECOFRAM) to identify, develop, and validate tools and methodologies to conduct probabilistic risk assessments. Under the ECOFRAM, terrestrial and aquatic workgroups have been established and have met on a monthly basis. PMRA and the EPA along with other stakeholders have worked together to review the current ecological assessment process and to develop probabilistic tools and methodologies. Thus far, both workgroups have defined the assessment questions concerned with the probability and magnitude of effects and have defined the major variables that influence effects on nontarget species. The workgroups have also developed a preliminary conceptual model for predicting exposure and ecological effects from the use of pesticides. In September the SAP agreed with the approach which the ECOFRAM is recommending. This proposal was presented at the American Chemical Society's (ACS) annual meeting and at the Society of Environmental Toxicology and Chemistry's (SETAC) meeting in December. Further presentations at other professional meetings are planned for 1998. A final workshop is planned for the Fall/Winter of 1998 to integrate the work of the two working groups.

A9. OECD Test Guidelines

PMRA and EPA have completed a survey on re-assessing the priority rankings for the development/updating of the OECD Test Guidelines related to chemical pesticides. On October 16, 1997, PMRA and EPA held a conference call to discuss priorities and coordinate our responses. The revised priority list will be reviewed at the National Test Guideline Coordinators Meeting in December.

PMRA and EPA are harmonizing approaches to requirements for field dissipation studies and are developing a new guidance document which will be offered to OECD for use as a prototype. PMRA and EPA are coordinating technical comments on OECD draft test guidelines for environmental fate and effects. Approaches for adsorption/desorption and aquatic metabolism

studies will also be harmonized. In November, EPA and PMRA met to develop a detailed work plan on how to coordinate strategies for approaches to nontarget terrestrial plant testing and for *Lemna* testing.

B. Joint Review of Chemical Pesticides Subcommittee

B1. Reduced Risk Chemicals (Cyprodinil)

Work on the review of cyprodinil has been moving ahead in accordance with, and in some areas, ahead of schedule. The experience has demonstrated that review processes and practices as well as technical assessments are largely compatible between EPA and the PMRA. Risk assessment and regulatory management practices have not yet been as thoroughly tested and may be more problematic. However, the availability of a practical example will identify challenges that may emerge and assist in developing generic solutions.

There is a keen interest, on the part of the US registrant to avoid procedural delays (that can emerge in any pilot program) that would limit consideration of almonds and grapes for the early California season, even though these are not part of the joint review. The Agencies are conscious of this legitimate concern and will give it consideration based on the fundamental conclusions arising from completed reviews.

Based on preliminary conclusions arising from the PMRA efficacy assessment, it appears that efficacy could make a useful contribution to “risk cup” analyses as required under the U.S. Food Quality Protection Act (FQPA).

B2. The Identification of Candidates for Joint Review/Work sharing

To date, reviews for approximately 55 compounds have been exchanged between EPA and PMRA. A further 20 compounds have identified as candidates for the exchange of reviews and the list will be considered by the Executive Board. These range from situations where reviews have been started in both countries to cases involving a new submission in one country for an active fully registered in the other. The spectrum covers the entire product range of traditional chemical pesticides, biopesticides, and antimicrobials.

Two additional candidates have been submitted for consideration for joint reviews. Unfortunately, these chemicals were not submitted to Canada and the U.S. at the same time. Experience to date is that the registrants submit to EPA first and if they pass the Reduced Risk screen, they then submit to PMRA. Once these chemicals have completed the PMRA screen, a decision will be announced. A revised procedure for Joint Reviews, which should help to avoid such problems in future, will be issued shortly stressing the following:

- 1) applications must be made simultaneously to both PMRA and EPA;
- 2) applicants must submit common data packages and use patterns;
- 3) a written request for a Joint Review must be submitted; and

- 4) a Comprehensive Data Summary (CDS) patterned after the EU format must accompany the registration application and supporting data packages in both countries.

The agencies are involved in an exploratory program to investigate cooperative evaluations on an international basis with Australia and Ireland. This initiative, like any pilot program, is not likely to yield immediate returns in terms of operating efficiencies or early registration decisions. However, it is contributing to experience and familiarity with international review standards, common dossiers and format, and comprehensive summaries.

B3. Information Sharing - Carbofuran

A report on the extensive field monitoring program undertaken in Canada (1997 season) was received in late October. PMRA and EPA will be cooperating in the review of this material with a view to developing compatible regulatory positions in December.

B4. Co-operative Re-evaluation/Re-registration of Heavy Duty Wood Preservatives

In view of the increasing global interest in pentachlorophenol and its contaminants, it has replaced creosote as the top priority for cooperation on the re-evaluation/re-registration of heavy duty wood preservatives. Initial action will be a scoping of the issue and the development of a strategic plan building on the extensive work that has already taken place..

The Project Team, comprised of representatives from PMRA and the EPA, met in Washington, September 15-18, 1997 to initiate discussions on the development of a strategy for the review of pentachlorophenol. The strategy will consider the active itself, dioxin and furan contaminants, and the disposal of treated wood. It is proposed to complete the review of pentachlorophenol by December 1998.

Work on creosote and chromated copper arsenate (CCA) will continue as part of the project. A reregistration decision on all of the heavy duty wood preservatives (CCA, creosote and pentachlorophenol) is targeted for December 1999.

B5. Data Requirements for Non-Agricultural (antimicrobial) Pesticides

EPA have forwarded to PMRA Data Evaluation Reviews of environmental and health data for five of the six targeted active ingredients. PMRA will consider these assessments in their review of these actives.

Progress has been made with an initial focus on heavy duty wood preservatives, as part of the Joint Review project. This will serve as a basis for more detailed discussions, regarding data requirements and approaches to risk assessment, applicable to other types of wood preservative products e.g. antisapstain. The PMRA has completed a detailed analysis/comparison of the US/Canada environmental data requirements for all antimicrobial use categories. This analysis was forwarded to EPA (Field and External Affairs Division and Antimicrobials Division) in October 1997.

Aimed at bringing the EPA & PMRA closer to a common 'tiered' approach to tox data requirements, Health Evaluation Division (HED) of PMRA and Antimicrobial Division (AD) of EPA held discussions in August focussed on the requirement for reproductive toxicity testing under the proposed rule, CFR 158.. In November HED sent a document on possible approaches to address reproductive toxicity to EPA for their review.

B6. Improved Coordination - Reregistration Process

In November PMRA provided EPA with information on the results of a survey on the efficacy of certain organophosphorous pesticides for consideration in the review of these active ingredients. EPA has identified priority candidates for consideration under the FQPA and the continuing reregistration program; a copy of the most recent working document was forwarded to PMRA in October. A comparison of review schedules for OECD countries, the EU, California, EPA, the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), and the PMRA has been initiated.

The pilot project to assess product labels with a view to identifying opportunities for risk reduction and use in IPM programmes has not been initiated.

C. Food Residues Subcommittee

C1. Trade Irritant Resolution

A consultative group composed of representative industry and grower groups was created in July. In August a preliminary draft of the criteria and a procedure for handling trade irritants within NAFTA countries was circulated to this group for comment. The comments received have been considered and a revised document is currently under review by the consultative group. The revised document was distributed to a wider range of stakeholders for final comment in November and will be available to the Executive Board in late December. Two issues which have yet to be resolved include the role of the regulatory agencies and stakeholders in the identification

and prioritization of trade irritants and whether uses which have time-limited tolerances should be considered outside the scope of this activity.

Status of specific trade irritants

EPA is continuing work to resolve specific trade irritants identified by NAFTA partners. Review of data to support a maximum residue limit (MRL) for chlorothalonil on non-bell peppers is on schedule and an MRL decision will be made by January 31, 1998. Work to establish an MRL for prometryn on carrots has been delayed by several weeks and an MRL decision is currently expected for December 15, 1997. Residue studies required to support MRLs for methamidophos on squash and strawberries were expected from the registrant in August 1997; to date, these studies have not been submitted, thus EPA is unable to commence work on resolving these trade irritants.

C2. NAFTA Guidance for the Establishment of Pesticide Tolerances/MRLs for Imported Commodities

The NAFTA TWG Work Plan stated that a draft of EPA Interim Guidance for Establishment of U.S. Import Tolerances would be available in October 1997, with a status report for the Executive Board Meeting December 3-4, 1997.

There are two parts to the U.S. import tolerance policy. Part I (non-science) contains the general statutory requirements, policies and procedures that will guide the U.S. in granting import tolerances. Part II (science) contains the data requirements that must be fulfilled in order for the U.S. to evaluate the safety of import tolerances. A draft of Part I is nearing completion and will be circulated to NAFTA partners as soon as it is available. EPA is revising Part II taking into account comments received from the U.S. FIFRA Science Advisory Panel, Canada, and stakeholders and will circulate to NAFTA partners in December 1997. The revised Part II, along with Part I, will be issued as interim EPA guidance.

The EPA document will serve as the basis for NAFTA wide guidance on establishing pesticide tolerances/MRLs for imported commodities which will be available by June 1, 1998.

C3. Development of Uniform Methodology for the Dietary Exposure Assessment of Pesticides

The goal of this project is to develop a NAFTA approach to dietary exposure assessments based on existing EPA guidance documents. This will also consider the incorporation of international guidance from two expert consultations convened by FAO and WHO (York, May 1995; Geneva, February 1997). The initial focus of the project is on the "*Draft EPA/Office of Pesticide Programs Policy for the Use of Anticipated Residues of Pesticides in Foods for Use in Chronic Dietary Exposure Assessments.*" PMRA sent comments to the EPA on this draft in November. A position paper on the use of probabilistic methodologies in Canadian dietary exposure assessments (acute and chronic) will be available by April 1 1998.

C4. Residue Chemistry Guidelines (RCGs) for Canada (Public Consultation Phase)

This project is essentially complete. The Canadian Guidelines were released to stakeholders for consultation on June 30, 1997 as a Regulatory Proposal (Pro 97-03). At the request of industry the comment period was extended from 60 to 90 days. The Guidelines are presently under revision based on the comments received. The final version of the document will contain a summary of stakeholder comments and PMRA responses with changes to the text highlighted. All comments have been considered and a revised draft of the Guidelines is under going peer review prior to publication as a Regulatory Directive by January 1998. The April 1, 1998 date for the application of the Residue Chemistry Guidelines to new submissions is unchanged.

The final document will be the basis for a project on the development of NAFTA Residue Chemistry Guidelines which will be considered at the full NAFTA TWG in June 1998.

C5. Definition of Acceptable Protocols for Residue Trials

One of the main objectives of the Food Residues Subcommittee is to establish a process for the development of North American Maximum Pesticide Residues Limits/Tolerances. A key component in this process are the field studies. It is important that the protocols for these studies are harmonized among the three NAFTA countries. As a first step to developing a NAFTA protocol information on existing protocols has been gathered from Mexico, the United States, Canada and international organizations (i.e., FAO) as well as from the pesticide industry.

A review of this information has been initiated and shall serve as the basis to determine the scope and structure of a NAFTA protocol.

C6. US/CDN Crop Field Trial Zone Map - Methodological Development and Implementation.

The US/Canada zone maps for crop field trials have been finalized. Although concern from industry stakeholders was expressed for some subzones in Canada, PMRA did not wish to revise these until a historical database is developed and experience gained in the use of the zones as presently proposed. It is recognized that as a result of experience in the implementation of the current proposal, as well as, other considerations related to the areas of agricultural production or cropping practices, that some of the current zones may need to be redefined. As an integral part of the Canadian Residue Chemistry Guidelines the zone maps will be implemented as of April 1, 1998.

In order to take advantage of the Canada/US residue zone maps additional guidance is needed to supplement the existing US residue data requirements. A first draft of the supplementary guidance will be available in December and finalized/implemented by April 1, 1998.

C7. Expansion of Residue Zone Maps to US/Mexico

In October, 1997, representatives from Statistics Canada made a presentation on a project for the development of Mexico's major and minor field regions to Mexican Regulatory Authorities (CICOPLAFEST) and the Mexican pesticide industry (AMIFAC). The process to develop this map shall involve the use of a geographic information system to register, integrate data layers input and delineate the field trial regions digital boundaries. The methodology will be similar to that used for the delineation of Canadian residue zones. AMIFAC has indicated a willingness to financially support the development of the maps. A detailed workplan is in preparation.

C8. Requirements for Field Residue Studies, Workshop in Mexico

This project is complete as in October, 1997, a workshop was held in Mexico on the "Regulation of Agrochemical Products". This workshop was a joint effort of the PMRA, EPA, CICOPLAFEST, the American Crop Protection Association (ACPA) and the Asociación Mexicana de la Industria Fitosanitaria, A.C. (AMIFAC).

Sixty-five participants from the Mexican pesticide industry (AMIFAC) and from Mexican regulatory authorities (CICOPLAFEST) attended the seminar. The workshop objectives were accomplished as the participants gained a better understanding of the procedures and requirements needed to establish pesticide MRLs/tolerances in food in the U.S., Canada and internationally (Codex Alimentarius).

D. Risk Reduction Subcommittee

D1. Integrated Pest Management (IPM) of Colorado Potato Beetle

The first working draft of an IPM document for Colorado potato beetle was distributed for Working Group input in May 1997. This draft included sections on the biology of Colorado potato beetle, a framework of IPM, and review of the various management tools. Work is underway to incorporate comments received and other information into a final version of the document which will be available by June 1, 1998.

D2. Integrated Pest Management in Canola

The Steering Committee met in Winnipeg, Manitoba (Canada) in August to review the draft framework document and to plan further actions for the development of an IPM approach in canola. Coordinators for insects, weeds, and diseases were identified with responsibility for gathering all available information on key pests in each of these areas. This information will then be entered into a pest complex/management practice matrix for organization and to identify those areas which lack adequate information and require research. In line with the workplan the pest management matrix will be presented for discussion at a meeting of the Canola IPM Working Group to be held December 10 in Saskatoon, Saskatchewan (Canada). This meeting will also

provide an opportunity to plan for the measurement of grower adoption of IPM in canola, and to discuss the benefits of IPM with a range of stakeholder groups.

D3. Biopesticide Joint Reviews

Procedures for applications for Biopesticide Joint Reviews were tabled at the June, 1997 NAFTA meeting. PMRA and EPA staff have been evaluating the joint review process in the interest of continued improvement.

Microbial Pesticides

Agrium Inc. submitted applications for registration to PMRA and EPA in June, 1997 for the use of *Burkholderia cepacia* strain Ran 3 on conifer and deciduous tree seeds, seedlings, and cuttings. As a result of the screening process, a joint letter from the two Agencies was sent to the registrant on September 17, 1997, indicating deficiencies in the submission. Work on this project is on hold pending a satisfactory response from the registrant.

Pheromones

Bedoukian and 3M submitted an application for registration in late October for the use of eastern pine shoot borer pheromone in forestry. The submission is being screened for acceptability. An acceptable submission will be reviewed in-line with the timetable established for Joint Reviews.

D4. Resistance Management Labelling

In December 1996, PMRA drafted and published a Regulatory Proposal (Pro96-03) for public consultation. EPA provided comments on April 30, 1997. Comments have also been received from Canadian researchers, pest control extension experts and the pesticide industry. Comments received to date indicate general support of the proposal although a few individuals question the value of this exercise.

PMRA is incorporating the comments received and will forward a revised document to EPA and CICOPALFEST in December, 1997, for further discussion and approval. This draft will be used to obtain stakeholder input in U.S. and Mexico. The goal is to have a NAFTA approach to Resistance Management Labelling for pest control products by September 1998.

OTHER ACTIVITIES OF THE NAFTA TWG ON PESTICIDES

At the meeting of the full NAFTA TWG in June the cochairs articulated a vision that within five years worksharing would be routine between the three countries. The motivation for this include

the following: simultaneous access to products for growers; access to new products more quickly; greater efficiency; reduced costs for testing; a reduction in the number of trade irritants; reduction in smuggling and subsequent enforcement costs; and consistency with the broader environmental and sustainable development goals of the NAFTA agreement. Initial “preconsultative” meetings have been convened with a limited number of stakeholders in Canada (October) and the US (December) to consider this concept further. Following these initial discussions a framework document will be circulated for broad stakeholder consultation.

Several documents related to the activities of the NAFTA TWG have been produced over the past year and are available from the Secretariat in the three countries. A list of these documents (Appendix I) and of the Secretariat representatives (Appendix II) is attached. Copies of these documents may also be obtained from the EPA Office of Pesticide Programs’ Public Docket located in Room 1132 of Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia; telephone 703-305-5805. Efforts are currently underway to make these documents available on the Internet; Canada: <http://www.hc-sc.gc.ca/pmra> and the U.S.: <http://www.epa.gov/oppfead1/nafta.htm>.

Appendix I

DOCUMENTS DEVELOPED BY THE NAFTA TECHNICAL WORKING GROUP ON PESTICIDES (NAFTA TWG)

General Documents

1. Joint Review of Reduced Risk Pesticide Data Submissions (March 21, 1996)
2. Harmonization of Environmental Data Requirements under NAFTA for Registration of Chemical Pesticides (May 5, 1997)
3. Joint Reviews for Biopesticides (May 26, 1997)
4. Restructuring the NAFTA TWG on Pesticides (May 27, 1997)
5. NAFTA TWG on Pesticides Terms of Reference (June 4, 1997)

Meeting Reports

1. NAFTA TWG on Pesticides Communiqué (March 27-29, 1996)
2. Report of the Second NAFTA TWG on Pesticides Meeting, June 2-4, 1997 (August 5, 1997; circulated with cover letter dated August 20, 1997)

Progress Reports

1. NAFTA TWG on Pesticides Progress Report (January 20, 1997)
2. NAFTA TWG on Pesticides Progress Report (November 17, 1997)

Project Sheets and Workplans (circulated with cover letter dated August 20, 1997)

Regulatory Capacity Building Subcommittee

1. Spray Drift and Deposit Model
2. Harmonization of Environmental Fate and Toxicology Study Protocols
3. Canada-US Map of Ecoregions for Terrestrial Field Studies
4. Electronic Submission and Review
5. Regulatory Aspects of Disease and Pest Control Products and Methods in Aquaculture
6. Harmonization of EU-OECD Guidance Documents for Preparation and Presentation of Submissions by Industry and Preparation of Evaluation Reports by Regulatory Agencies
7. Harmonization of Occupational/Bystander/Residential Exposure Assessment
8. Assessment of Feasibility of Probabilistic Tools and Methods for Ecological Assessments
9. OECD Test Guidelines

Joint Review of Chemical Pesticides Subcommittee

1. Reduced Risk Chemicals (Cyprodinil)
2. The Identification of Candidates for Joint Review/Work sharing
3. Information Sharing - Carbofuran
4. Co-operative Re-evaluation/Re-registration of Heavy Duty Wood Preservatives
5. Data Requirements for Non-Agricultural (antimicrobial) Pesticides
6. Improved Coordination - Reregistration Process

Food Residues Subcommittee

1. Trade Irritant Resolution
2. NAFTA Guidance for the Establishment of Pesticide Tolerances/MRLs for Imported Commodities
3. Development of Uniform Methodology for the Dietary Exposure Assessment of Pesticides
4. Residue Chemistry Guidelines for Canada
5. Definition of Acceptable Protocols for Residue Trials
6. US/Canadian Crop Field Trial Zone Map - Methodological Development and Implementation
7. Expansion of Residue Zone Maps to US/Mexico
8. Requirements for Field Residue Studies Workshop in Mexico

Risk Reduction Subcommittee

1. Integrated Pest Management of Colorado Potato Beetle
2. Integrated Pest Management in Canola
3. Joint Review of a Pheromone
4. Joint Review of a Microbial Pesticide
5. Resistance Management Labelling

Appendix II

NAFTA TWG ON PESTICIDES SECRETARIAT REPRESENTATIVES

Canada

Bill Murray, Regulatory Affairs and Innovations Division, tel: 613-736-3671, fax: 613-736-3699, email: bmurray@pmra.hwc.ca

Jennifer Ballantine, Regulatory Affairs and Innovations Division, tel: 613-736-3690, fax: 613-736-3699, email: jballantine@pmra.hwc.ca

Mexico

Gustavo Olaiz, Director General de Salud Ambiental, SSA, tel: 525-203-5011, fax: 525-203-4863, email: saludamb@mpsnet.com.mx

Cristina Cortinas, Asesora de la Presidencia del INE y Coordinadora de la Unidad de Substancias Químicas y Evaluación Ambiental del INE, SEMARNAP, tel: 525-624-3589, ext. 93, fax: 525-624-3595, email: jmtz@correo.uam.mx

United States

Kennan Garvey, Field and External Affairs Division, tel:703-305-7106, fax:703-308-1850, email: garvey.kennan@epamail.epa.gov

Tracy Perry, Field and External Affairs Division, tel:703-305-7461, fax:703-308-1850, email: perry.tracy@epamail.epa.gov